Abstract

Background: Transparent reporting of clinical research is essential to the external validity of any study. Reporting guidelines or checklists are available and endorsed for most types of research trial designs (i.e., randomized controlled trials, systematic reviews, etc). These tools promote the inclusive reporting of a minimal set of information important to the end user and improve the likelihood of knowledge translation. The objective of this study was to create a similar reporting guideline or checklist for clinical pharmacokinetic studies via consensus generation among key stakeholders.

Methods: Consensus was to be achieved using a modified Delphi survey method among key stakeholders. Study participants were purposefully selected and self-proclaimed to be key stakeholders as either clinical pharmacokinetic researchers or knowledge users. Four rounds of the modified Delphi survey and a series of small group teleconferences were required to generate consensus around items worthy of inclusion in to a minimum dataset that would inform the transparent reporting of clinical pharmacokinetic studies.

Results: Sixty-eight key stakeholders consented to participate in this study from nine different countries. Consensus was achieved for 24 separate items to be included in the checklist.

Conclusions: The external validity of pharmacokinetic research can be greatly compromised by incomplete study reporting. Using consensus generation methods among key stakeholders we have developed a tool to be used by researchers and knowledge users to ensure transparent and complete reporting of clinical pharmacokinetic studies. Adoption and endorsement of these guidelines will ensure more complete reporting of these studies and allow for better assessment of utility at the bedside.